UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

BAILEY SILVERMAN, *et al.*,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	CIVIL ACTION H-10-1952
	§	
WATSON PHARMACEUTICALS, INC., *et al.*,	§	
	§	
Defendants.	§	

ORDER

Pending before the court are defendant Capsugel, Inc.'s motion to exclude portions of the opinion testimony of Dr. Linda Motyka (Dkt. 67), and defendants Watson Pharmaceuticals, Inc. and Watson Pharms, Inc's (collectively the "Watson defendants") motion to exclude expert testimony of Dr. Linda Motkya (Dkt. 74). Upon consideration of the motions, the responses, the replies, and the applicable law, both motions are DENIED.

BACKGROUND

Bailey Silverman was prescribed the blood pressure medication Taztia XT, which was manufactured by the Watson defendants using gelatin capsules made by defendant Capsugel. She alleges that she suffered arsenic poisoning from elevated levels of arsenic present in the hard gelatin capsules. As a part of their case, the Silvermans proffered expert witness Dr. Linda Motyka. Dr. Motyka has a Ph.D. in organic chemistry and over 25 years in the pharmaceutical industry. Notably, the first 10 years after completing her doctorate, she worked in positions directly responsible for regulatory affairs for pharmaceutical companies. Based on her experience and a review of the documents in the case, Dr. Motyka drew the following conclusions: (1) Watson did not properly investigate Bailey Silverman's complaint; (2) Watson violated many Food and Drug Administration

("FDA") Good Manufacturing Practices; (3) Capsugel failed to elaborate and clearly define the term "Process monitoring data" on its Certificates of Analysis for the capsules supplied to Watson; (4) Watson did not request testing by Capsugel; and (5) Watson failed to audit Capsugel's testing of its capsules. *See* Dkt. 90, Ex. A. Both Capsugel and Watson move to exclude portions of Motyka's testimony.

LEGAL STANDARD

The Supreme Court of the United States acknowledged in *Daubert v. Merrell Dow Pharmaceuticals* that Federal Rule of Evidence 702 serves as the proper standard for determining the admissibility of expert testimony. *Daubert v. Merrell Dow Pharms*., 509 U.S. 579, 597–98, 113 S. Ct. 2786 (1993). Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion, or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Under *Daubert*, a trial court acts as "gatekeeper," making a "preliminary assessment of whether the reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93; *Kumho Tire v. Carmichael*, 526 U.S. 137, 147, 119 S. Ct. 1167 (1999); *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 243–44 (5th Cir.2002). *Daubert* and its principles apply to both scientific and non-scientific expert testimony. *Kumho Tire*, 526 U.S. at 147. Experts need not be highly qualified to testify, and differences in expertise go to the weight of the testimony, rather than admissibility. *Huss*, 571 F.3d at 452. Nonetheless, courts need not admit testimony that

is based purely on the *ipse dixit* of the expert. *Gen. Elec. Co. v. Joinder*, 522 U.S. 136, 146, 118 S. Ct. 512 (1997); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998).

In addition to being qualified, an expert's methodology for developing the basis of his or her opinion must be reliable. *Daubert*, 509 U.S. at 592–93; *Moore*, 151 F.3d at 276. Even if the expert is qualified and the basis of her opinion reliable, the underlying methodology must have also been correctly applied to the case's particular facts in order for her testimony to be relevant. *Daubert*, 509 U.S. at 593; *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 352 (5th Cir. 2007). The party proffering expert testimony has the burden of establishing by a preponderance of the evidence that the challenged expert testimony is admissible. *See* Fed. R. Evid. 104(a); *Moore*, 151 F.3d at 276. The proponent does not have to demonstrate that the testimony is correct, only that the expert is qualified and that the testimony is relevant and reliable. *Moore*, 151 F.3d at 276.

ANALYSIS

1. Capsugel's Argument

Capsugel argues that the court should exclude Dr. Motyka's opinion that Capsugel's use of the terms "reduced frequency testing" and "process monitoring data" should have been clearer because this opinion is based solely on her own subjective opinion and not on any identifiable literature, FDA regulation, or standard in the U.S. Pharmacopeial Convention. Capsugel contends that this makes Motyka's opinion pure *ipse dixit* and, therefore, excludable because it is unreliable. The court disagrees. In *Joiner*, the Supreme Court stated that

> nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

522 U.S. at 146. Here there is no great analytical gap. Dr. Motyka explained, based on her years of experience, the function of a Certificate of Analysis. She further opined on the effect of the terms "reduced frequency testing" and "process monitoring data" in the context of a Certificate of Analysis. Right or wrong, her opinion is not an enormous leap from the data. And, Capsugel's criticisms of her opinion go the weight of her testimony, not the admissiblity, and are proper subjects for vigorous cross-examination. Accordingly, Capsugel's motion to exclude portions of Dr. Motyka's opinion testimony is denied.

2. The Watson Defendants' Arguments

The Watson defendants argue that Dr. Motyka's testimony should be excluded for five reasons. First, they contend that Motyka should not be allowed to testify regarding Watson's investigation of the Silverman complaint. The Watson defendants argue that Dr. Motyka's own testimony demonstrates that the investigation is irrelevant because it occurred after the alleged ingestion. The testimony is therefore highly prejudicial and should be excluded. Plaintiffs counter that the Watson defendants mischaracterize Motyka's testimony. In fact, they urge, that Motyka explained that Watson simply failed to test the reserve samples in violation of their own procedures and good manufacturing practices. This, they argue, is directly relevant to the issues at hand. The court agrees to the extent that it cannot hold that her testimony is irrelevant at this point. Therefore, the court will not exclude it.

Second, the Watson defendants argue that Motyka's opinion invades the province of the FDA, which has the primary jurisdiction to establish good manufacturing practices and enforce compliance. Plaintiffs counter that the Watson defendants' primary jurisdiction argument is untimely, presented in the wrong procedural vehicle, and inapplicable to this case. Further, they

argue that the FDA's actions—assuming it took any—have no preclusive affect on the plaintiffs' claims. Plaintiffs are correct.

The primary jurisdiction doctrine allows a court to refer specific matters to an administrative agency where issues arise that are within the purview and competence of the agency, and the agency's determination could materially aid in deciding the issue before the court. *Miss. Power & Light Co. v. United Gas Pipeline Co.*, 532 F.2d 412, 417–18 (5th Cir. 1976). "No fixed formula exists for applying the doctrine of primary jurisdiction." *Id.* at 419. "The courts should be reluctant to invoke the doctrine of primary jurisdiction, which often, but not always, results in added expense and delay to the litigants where the nature of the action deems the application of the doctrine inappropriate." *Id.* "Deference is particularly inappropriate where the litigation deals with a single event which requires no continuing supervision by the regulatory agency." *Id.* Here, the purpose of the doctrine would not be served by placing the case on hold while the FDA takes some action. It is not at all clear that the agency intends to take any action. And, this case is about an incident rather than a sweeping practice. Accordingly, even assuming a motion to exclude expert testimony was the proper vehicle for a primary jurisdiction argument—which is not a given—the doctrine is not applicable on these facts.

Third, the Watson defendants ask the court to exclude Dr. Motyka's testimony that the Watson defendants violated good manufacturing procedures because the FDA has not made such a finding. Plaintiffs respond that Dr. Motyka's opinion that the Watson defendants violated FDA standards is relevant. The parties disagree whether Dr. Motyka's opinion on what the FDA regulations require is the generally accepted interpretation of the regulations or a novel interpretation based solely on her own opinion. Since it is unclear which direction she intends to take on the stand, the court will not exclude her testimony at this point. Dr. Motyka may testify to industry standards,

based on her experience. She may not, however, testify regarding the legal interpretation of the regulations. That is the province of the court. Accordingly, Dr. Motyka's testimony that the Watson defendants failed to comply with good manufacturing practices will not be excluded.

Fourth, the Watson defendants move the court to exclude Dr. Motyka's testimony that the Watson defendants failed to audit Capsugel for testing of the capsules during its 2006, 2007, and 2008 audits. They argue that in so testifying, Motyka creates new obligations not present in the regulations. Plaintiffs argue that Dr. Motyka will testify that the regulations required the Watson defendants to perform testing on the capsules to validate Capsugel's results and that the Watson defendants failed to do so. As above, the court reminds the parties that Dr. Motyka is not a legal expert. However, she may testify regarding industry standards and she may testify regarding the Watson defendants' actions. Thus, the court will not exclude her testimony at this time.

Last, the Watson defendants argue in general that Dr. Motyka should not be allowed to testify because she offers no expert analysis. Instead she merely summarizes parts of documents in the record and regurgitates the regulations. However, the court has read her expert report and her deposition testimony and disagrees. Accordingly, the court will not exclude her testimony.

CONCLUSION

Pending before the court are defendant Capsugel's motion to exclude portions of the opinion testimony of Dr. Linda Motyka (Dkt 67), and the Watson defendants motion to exclude expert testimony of Dr. Linda Motkya (Dkt. 74). Upon consideration of the motions, the responses, the replies, and the applicable law, both motions are DENIED.

It is so ORDERED.

Signed at Houston, Texas on April 8, 2013.

Gray H. Miller
United States District Judge